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10/052,771

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John A. Schillinger

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07/17/2009

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EXAMINER

PARA, ANNETTE H

ART UNIT

PAPER NUMBER

1661

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/052,771 | <b>Applicant(s)</b><br>SCHILLINGER ET AL. |  |
|                              | <b>Examiner</b><br>ANNETTE H. PARA   | <b>Art Unit</b><br>1661                   |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04032009, 07022009</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

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DETAILED ACTIONClaim Rejections - 35 USC § 103

Claims 1, 2, 4-10, remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Barry *et al* (U.S. Patent 5,463,175) in view of Strauch *et al*. (U.S. Patent 5,276,268) and Kishore *et al*. (U.S. Patent 5,312,910) and in further view of Shah *et al* (U.S. Patent 5,188,642).

Barry *et al* teach introducing a transgene encoding the glyphosate tolerant GOX (glyphosate oxidase) and a transgene encoding a sulfonylurea-resistant form of the maize acetolactate synthase gene (ALS) into a corn cell (columns 37 and 38). Barry *et al* teach using selecting transformed corn cells on both glyphosate and chlorsulfuron. Barry *et al* teach a glyphosate tolerant corn plant at claim 22.

Barry *et al* do not specifically teach introducing both a glyphosate tolerant CP4 EPSPS or a GOX transgene and an ALS transgene into a soybean. Barry *et al* do not teach a plant with a phosphinothricin-resistance gene.

Strauch *et al*. teach isolating and incorporating in plant the PTC gene resistant to glufosinate herbicide

Shah *et al* teach a transgene encoding a petunia EPSPS enzyme resistant to glyphosate and a soybean and cotton plant transformed therewith (claims 19 and 23).

Kishore *et al* teach a transgene encoding a maize EPSPS enzyme resistant to glyphosate and a method of using a plant transformed therewith to selectively control weeds in a field (claim 5). Kishore *et al* teach that soybean, cotton and maize can be transformed with said transgene (column 5, lines 59-62).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to use the teachings of Barry *et al* to introduce both a GOX transgene and an herbicide resistant PCT transgene into soybean and regenerate a transgenic herbicide resistant plant. Barry *et al* teach that plants, which can be made glyphosate tolerant, include soybean at column 26, line 45, and claim 22. Given the success of Barry *et al* in introducing both of said transgenes into corn cells and selecting transformants on chlorsulfuron, and demonstrated that the GOX transgene produced Roundup (glyphosate) tolerance in transgenic soybean (columns 37 and 38) one of ordinary skill in the art would have had a reasonable expectation of success. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Barry *et al* to use

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the glyphosate tolerant EPSPS transgene of Shah *et al* combined with a herbicide tolerant PCT transgene of Strauch *et al.* to transform soybean plants. The use of herbicide resistant plants to control weeds by application of the corresponding herbicide was obvious to one of ordinary skill in the art in view of the teachings of Kishore *et al.*

Response to Applicants arguments

Applicants' arguments filed on 03 April, 2009 have been fully considered but are not found to be persuasive.

Applicants argue that the skilled artisan would not read Barry *et al.* as teaching that two herbicide resistance genes could or should be combined into a soybean plant to yield tolerance to both herbicides (page 6, 1<sup>st</sup> paragraph of the Response). This is not found to be persuasive. It is the Examiner's opinion that one of ordinary skill in the art would have found such a combination obvious given Barry's success in expressing multiple transgenes for herbicide resistance in a single plant.

Applicants argue that that patent (5,593,874 Brown *et al.*, **not cited as prior art**) does not teach or suggest any benefit to the resistant ALS gene in the plant cells other than as a selectable marker, i.e., to identify transformed cells. Applicants argue that a further examination of Example 5 of Barry *et al.* also confirms that any use of resistance to sulfonylureas was contemplated only for selection of *in vitro* cells co-transformed with a different gene of interest, since only GOX levels were evaluated, and there was no suggestion that EC9 was useful for anything other than *in vitro* experiments (page 6, 2<sup>nd</sup> paragraph of the Response). This argument is not found to be persuasive given the art recognized that sulfonylurea herbicide resistance in a crop plant was desirable. Brown *et al* state that "enzymes suitable for use in this invention are acetolactate synthase..." (column 6, lines 59-60).

Applicants argue that Dr. Feng (Declaration filed under 37 CFR § 1.132) further points out that the BMS cells used in the experiments described in Example 5 of Barry *et al.* are not regenerable into whole plants, which also points against Barry *et al.* suggesting whole plants resistant to two herbicides. Applicants argue that in light of the above discussion, it is clear that Barry *et al.* does not teach or suggest the stacking of a sulfonylurea-resistant ALS gene with a glyphosate resistance gene to create the claimed plants and seeds (page 7, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs of the Response). This argument is not found to be persuasive. At the time of Applicants' invention it was well known that BMS cells were not regrettable, but it was well known that transformed soybean cells were regenerable. This is not a teaching away of the instant claims.

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Applicants argue that Barry *et al.* used a maize sulfonylurea-resistant ALS gene to transfect non-regenerable corn cells. Applicants argue that that would in no way lead the skilled artisan to believe that a maize sulfonylurea-resistant ALS gene would make soybeans resistant, particularly when in combination with a second herbicide tolerance transgene (page 7, 4<sup>th</sup> paragraph of the Response). This argument is not found to be persuasive as addressed above.

Applicants argue that the Declaration of Dr. Paul Feng under 37 C.F.R. §1.132, additionally provides a summary of experiments establishing that the stacking of two glyphosate resistance genes, GOX and CP4, did not lead to increased glyphosate resistance in corn, tobacco and cotton, contrary to what would be predicted. Applicants argue that this further establishes that stacking of herbicide resistance traits is not a priori predictable as is assumed in the Action, and that there would not have been any reasonable expectation that a benefit would be obtained by stacking a transgene conferring resistance to glyphosate herbicide and a transgene conferring resistance to ALS inhibitor herbicides in a soybean (paragraph spanning pages 7-8 of the Response). This argument is not found to be persuasive because it is not directed to the specifics of the instant claims, directed to a soybean (seed) comprising a transgene for glyphosate and an ALS inhibitor herbicide resistance.

Applicants argue that there was also no reasonable expectation that such a plant would have a commercially acceptable yield as required in claim 13, or that a soybean plant could be treated with an amount of ALS inhibitor or glyphosate herbicide in an amount effective to control weeds without injury to the plant, as required in claim 53, especially if a tank mix of these herbicides were applied to the plant recited in claim 13. Applicants argue that there was no expectation that a soybean plant could be produced, engineered with transgenes conferring resistance to glyphosate herbicide and ALS inhibitor herbicides, wherein the yield of the plant is unaffected by the presence of the transgenes as recited in claim 61 (page 8, 2<sup>nd</sup> paragraph of the Response). These arguments are not found to be persuasive. One of ordinary skill in the art at the time of Applicants' invention would have readily recognized that sufficient screening of transformants would have been required as routine experimentation to identify transformants that are sufficiently resistant to field levels of herbicides and retain commercially acceptable grain yield.

Applicants argue that additional uncertainty of any benefit from stacking the specified herbicide tolerance transgenes came from the fact that expression of herbicide resistance transgenes requires manipulation of complex

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metabolic pathways in plant cells, including in numerous diverse tissues found throughout the plant, and expression of enzymes not normally present in a plant creates a "metabolic drag" reducing energy by diverting resources to the expression of a transgene(s), combined with the uncertainty of potential interactions among inter-related metabolic pathways. Applicants argue that Dr. Byrum, in his Declaration provided as Appendix 2 of the response dated October 9, 2007, points out at page 3 that "[h]erbicide resistance traits add the uncertainty of potential interactions among interrelated metabolic pathways, including negative or positive feedback regulation of different pathways from altered substrate or precursor production." (page 8, 1st paragraph of the Response). This argument is not found to be persuasive because the instant claims are not directed to combining glyphosate and glufosinate resistance in a transgenic soybean.

Applicants argue that since a corn sulfonylurea-resistant ALS, as utilized in Barry *et al.* for selection of transformed corn cells, is not normally present in soybeans. Applicants argue that a glyphosate resistant EPSPS gene is also not normally present in soybeans. Applicants argue that a soybean plant does not normally express those enzymes that confer herbicide tolerance in the appropriate amount and tissues that confer the herbicide tolerance. Applicants argue that one of skill in the art could just as easily have expected the mutant and native enzyme forms to interfere with each other, such as through co-suppression. Applicants argue that engineering new patterns of expression of important metabolic enzymes in non-native forms, especially two enzymes that are closely linked with the same pathways, would certainly cause doubts about whether such pathways could function to provide herbicide tolerance, let alone a high yielding plant with normal seeds (paragraph spanning pages 9-10 of the Response). These arguments are not found to be persuasive. Kishore *et al* teach introducing a glyphosate tolerant EPSPS encoding transgene into soybean (page 10 of the Office action mailed 9 April 2007). Clearly the prior art had a reasonable expectation of success in making a transgenic soybean tolerant to glyphosate at the time of Applicants' invention. Sathasivan, *et al* teach transgenic plants and seed comprising a transgene conferring resistance to ALS inhibitor herbicides (claim 12, claim 16) including soybean (column 9, line 4) and a method of weed control using said transgenic plant (claim 19) and wherein an imidazolinone is used in combination with a second herbicide (claim 20).

Applicants argue that mixtures of herbicides are not predictable in the amount of damage they cause in relation to each herbicide alone, as illustrated in U.S. Patent 5,599,769 (Hacker *et al.*), and that uncertainty would have further added to the unpredictability of the resistance of the claimed soybean to tolerate both glyphosate and a

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sulfonylurea as of the filing date of the parent case. Applicants argue that [instant] claim 55 requires that the transgenic soybean plant is treated with a tank mix of an ALS inhibitor and glyphosate herbicides in an amount effective to control weeds without injury to the plant. since the synergy exhibited by a combination of glyphosate and a sulfonylurea was unpredictable, it would not have been known whether routine experimentation was sufficient, since no plant having the claimed combination of herbicide resistance genes might be able to overcome the synergistic effect of the herbicide combination, without additional unpredictable manipulation, e.g., with the use of a particular promoter or targeting sequence. Applicants argue that this point would thus have added further uncertainty as to whether the invention plant would be resistant to the combination of herbicides, and would have made the skilled artisan conclude at the time of filing that there was not a reasonable expectation of success in the claimed invention, particularly when this uncertainty is combined with the uncertainties discussed above (page 10 of the Response). This argument is not found to be persuasive. One of ordinary skill in the art at the time of Applicants' invention would have readily recognized that standard selection and experimentation would have been required to select transgenic soybean plants capable of growing in the presence of an effective amount of two herbicides.

Applicants argue that one of skill in the art would have been aware as of the filing date of numerous studies asserting that the presence of a glyphosate tolerance gene resulted in yield suppression in soybeans, compared to varieties lacking a glyphosate tolerance transgene. Applicants argue that one of skill in the art would have therefore been taught away from attempting to combine a glyphosate tolerance transgene with a gene conferring sulfonylurea tolerance given the potential impact on yield and the great importance of yield in soybeans. Applicants argue that Raymer and Grey, *Crop Science* 43:1584-1589 (2003), at pages 1585-1586, summarizes data from field trials from 1995-1996 showing an apparent reduction in yield when glyphosate-tolerant soybean lines were compared with comparable conventional varieties. Applicants argue that Marking, *Corn and Soybean Digest* March 15, 1999, discuss several studies dating from 1996 that find a "yield lag" due to the glyphosate resistance trait. Applicants argue that Marking concludes, "[t]his yield lag factor for RR soybeans has been mentioned by many scientists and top-end growers who made side-by-side comparisons since 1996..." Marking, third paragraph from the bottom. Applicants argue that the above two references were provided in Appendix 1 filed with the response of October 9, 2007. Applicants argue that at the time of filing, glyphosate tolerance was believed to result in yield loss in soybeans, the Action cites a passage of Raymer and Grey citing another study that found no difference in yield

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between glyphosate resistant Roundup Ready (RR) soybeans and nontransgenic parental lines. Applicants argue that when the studies discussed above showing reduced yield in RR varieties are taken into consideration, the skilled artisan at the time of filing would believe that there was a strong likelihood that a herbicide resistance gene leads to a reduction in yield. Applicants argue that the skilled artisan would have reasoned that, if one herbicide resistance gene causes a reduction in yield, then stacking two herbicide resistance genes in one plant would likely lead to an intolerable reduction in yield. Applicants argue that the finding in the specification that soybean plants with stacked herbicide tolerance traits can be produced without a yield deficit is therefore particularly surprising and unexpected (paragraphs spanning pages 11-12 of the Response). These arguments are not found to be persuasive and have been substantially addressed in the Office action mailed 7 November 2008 (page 4, 1<sup>st</sup> paragraph, page 8, 1<sup>st</sup> paragraph).

Applicants argue that Barry et al. does not teach or suggest the claimed invention because Barry et al. did not teach or suggest using the herbicide-resistant ALS gene to create a transgenic plant resistant to sulfonylurea herbicides. Applicants argue that there would not have been a reasonable expectation of success at the time of filing because of uncertainty regarding the suitability and yield of the claimed plant both when untreated and treated with glyphosate and a sulfonylurea. Applicants argue that the prior art taught away from the present invention by indicating that there is a likelihood of a reduced yield with a single herbicide resistance gene, and therefore stacking two such genes in a single plant would have been expected to reduce yield even further, while it is widely accepted that high yield is the single most important trait in soybeans. Applicants argue that the claimed plants achieved unexpected results, since plants with the combination of genes overcame the synergistic damage normally caused by mixes of glyphosate and ALS inhibitors (paragraph spanning pages 12-13 of the Response). Applicants argue that the cited Shah et al., Kishore et al., and Wilson references do not cure the defect of Barry ('175), in view of the lack of an expectation of success, the teaching away found in the art of the time, and the unexpected results obtained in the present invention (page 13, 2<sup>nd</sup> paragraph of the Response). These arguments are not found to be persuasive. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).



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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1, 2, and 4-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,376,754 has been withdrawn in view of the Applicants’ argument.

Claims 1, 2, 4-10 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,710,368. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species of the claims of the issued patent render obvious the genus encompassed by the instant claim.

Applicants argue that they disagree with the assertion in the Action that the instant claims are generic to the claim of the ‘368 patent.

This is not found persuasive because examiner never stated that the instant claims were generic to the claims of the ‘368 patent but stated that the **species** of the claims of the issued patent render obvious the **genus** encompassed by the instant claim.

### **Conclusion**

No claims are allowed.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette H. Para whose telephone number is (571) 272-0982. The examiner can normally be reached Monday through Thursday from 5:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975. The fax number for the organization where the application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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/Annette H Para/  
Primary Examiner

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